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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/095,385	06/10/98	MORRISON S	30435.45USU1

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EXAMINER	
ZEMAN, M	
ART UNIT	**PAPER NUMBER**
1631	15

DATE MAILED: 05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/095,385	Applicant(s) MORRISON ET AL.	
	Examiner Mary K Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *13 March 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *16-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☒ Interview Summary (PTO-413) Paper No(s). *15* .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1631**.

Claims 1-27 are pending in this application. Claims 16-27 remain withdrawn from consideration as being drawn to a non-elected invention. Claims 1-15 are under examination.

Applicant's arguments filed 3/13/00 have been fully considered but are moot in view of the new grounds of rejection. The declaration of Dr. Morrison has also been fully considered, and will be addressed below.

All non-reiterated rejections are withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated by Weltzin et al. (US Patent 5,534,411).

Claim 14 is product-by-process type claim, wherein the claim is drawn to a product (IgA) made by a particular process (transfection of an Ig producing cell with SC).

The MPEP discusses product-by -process claims in chapter 2100: "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP 2113.

Weltzin et al. sets forth recombinant IgA molecules that comprise secretory component. The methods of Weltzin et al. are very similar to those of the claimed invention. Whether the product resulting from the process is the same, is not clear, and the Office does not have the facilities to perform such comparative analyses. In a discussion of product-by-process claims, this court has said: "[W]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 59 CCPA 1036, 1041, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972). The court further addressed the issue of product-by process claims in In re Best: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). Applicant argues that because the antibodies are made by a differing process, the resulting antibodies are different. Applicant has not provided evidence distinguishing the claimed compositions over the antibodies produced by Weltzin et al.

Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated by Hein et al (US Patent 5,959,177).

Hein et al. set forth recombinant IgA molecules that comprise secretory component. The methods of Hein et al. produce dimeric IgA with Secretory Component that appear to be the same as those being claimed. The antibodies of Hein et al. are secreted, and bind appropriate antigens. Whether the product resulting from the process is the same, is not clear, and the Office does not have the facilities to perform such comparative analyses. In a discussion of product-by-process claims, this court has said: "[W]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of

the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 59 CCPA 1036, 1041, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972). The court further addressed the issue of product-by process claims in In re Best: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). Applicant argues that because the antibodies are made by a differing process, the resulting antibodies are different. Applicant has not provided evidence distinguishing the claimed compositions over the antibodies produced by Weltzin et al.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weltzin et al. (US Patent 5,534,411) in view of Hein et al. (US Patent 5,959,177).

The claims are drawn to methods of producing a secretory Ig from cells producing both Ig and secretory component, and Ig molecules so produced. IgA is a preferred Ig, and the cell type is not limited.

Weltzin (US Patent 5,534,411) discloses such a method at column 11. "In another method, the IgA-secreting hybridoma cells are transfected with an expression vector containing the cDNA for secretory component. The resulting cells produce IgA-secretory component complexes." Weltzin discloses methods of culturing IgA secreting hybridomas, methods of collecting the IgA and methods of purifying the IgA. Weltzin also discloses pharmaceutical preparations of the antibodies with a pharmaceutically acceptable carrier, and/or an adjuvant. (See Example 3) The preferred antibody of Weltzin is a monoclonal IgA produced by a mouse hybridoma, and is specific for RSV antigens (HNK20). Weltzin does not provide an example of this method.

Hein et al. (US Patent 5,959,177) discloses methods of using plants to produce secretory IgA which comprise heavy chain, light chain, J chain and Secretory Component (SC). (column 63 line 45 to column 70 line 12) Hein et al. first create plant cells producing IgA heavy and light chain. Antibodies produced by that plant are tested for activity and binding. Next, the Ig producing plants are crossed with a third plant comprising the J chain sequences. Hein et al. discover that mostly dimeric IgA is produced in the progeny plant cells, and some polymeric forms as well (column 69 lines 1-20). The antibodies are correctly folded and assembled, and bind relevant antigen. Finally, Hein et al. cross the IgA/ J Chain plants with a plant comprising SC sequences. The antibodies produced by progeny plants are properly assembled, and are about 45% of the total antibody population produced. These sIgA molecules bind the relevant antigen at least as well as the natural monoclonal antibody (column 71 lines 24-27). Hein et al note that the ability of a single plant cell to produce secreted IgA was unexpected in view of the unique pathways naturally used in the production of sIgA (Column 71-72).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have transfected an Ig producing cell with the sequences encoding SC, to produce a secretory Ig (sIg). Weltzin provides the explicit suggestion to transfect a monoclonal hybridoma with the SC sequences to obtain a secreted IgA. Hein et al. produce such sIgA antibodies in plants, wherein the assembly of the antibody, the dimerization of the IgA molecules and the addition of the SC all occur in one cell, indicating that proper assembly and binding activity can be achieved in one cell. The disclosure of Hein et al. provide the sequences of SC, the J Chain, heavy and light chains, as well as vectors, and promoters as well as domain modification of the antibodies. The teachings of Hein et al. provide a reasonable expectation that one of skill in the art would have had success in obtaining sIgA from a single cell producing IgA, after transfection with sequences encoding SC.

Applicant has provided the declaration of Dr Morrison in rebuttal of the previous art rejections. This declaration has been thoroughly considered, but does not overcome this new grounds of rejection.

Dr Morrison discusses the state of the prior art at the time the invention was made, and characterizes it as having no expectation that the claimed method would work, in view of the

general understanding of how IgA molecules become sIgA molecules. The complex pathways that natural IgAs take, Morrison suggests, teaches away from using a single cell method. However, by at least May, 1996, to which Hein et al. have priority, such a one cell production method of functional sIgA was possible, and had been reduced to practice. Dr Morrison also makes the following points in her declaration: a) that there was uncertainty whether polymeric IgA would be bound by SC outside of its normal pathway. Hein et al. showed that dimeric and polymeric IgA were bound by SC; b) that there was uncertainty whether soluble SC would bind IgA. Again, Hein et al. provided a reasonable expectation that soluble SC would bind IgA, as the assembled IgA of Hein et al. bound SC and J chain.; c) uncertainty whether the natural transcytotic pathway was necessary for the production of sIgA. Hein et al. demonstrated that the transcytotic pathway is not necessary; d) and uncertainty as to whether or not a non-epithelial cell could produce sIgA. Hein et al. disclosed that plant cells (a non-epithelial cell) can produce sIgA.

Applicant further notes that the SC of the plant antibodies is smaller than the full length SC. While that is true, it is not necessarily relevant, as Hein et al. pointed out that SC exists in a variety of forms naturally, including smaller forms (column 69 lines 37-40). Additionally, the claims are not limited to production of sIgA having a full-length SC. As such, the declaration is not persuasive.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center receptionist whose telephone number is (703) 308-0196.

mkz

May 19, 2000

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP ~~1600~~
AU 1631